UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENLAB USA LLC, Plaintiff, v. ESTAR TECHNOLOGIES LTD., ECLIPSE AESTHETICS LLC, HEALEON MEDICAL, INC., Defendants.	)	Civil Action No. 1:16-cv-8771

MEMORANDUM IN SUPPORT OF DEFENDANTS ECLIPSE AESTHETICS, LLC, AND HEALEON MEDICAL, INC. MOTION FOR PRELIMINARY INJUNCTION AND STAY

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I. Introduction

There are significant differences between a manufacturer of a product, a reseller of a product, and an end user of a product. Each has a specific point in the life span of a product. A manufacturer creates the product, the reseller sells the product, and an end user utilizes the product. With this in mind, patent law allows a patentee to prevent others from making, using, or selling a patented product. However, a patent covering only a specific method of use of a product does not allow the patentee to prevent others from making, using, or selling an unpatented product as Plaintiff is attempting in the present case.

Plaintiff initially filed suit in November 2016 against the manufacturer (Estar Technologies Ltd.) of products used by medical providers to create Platelet Rich Plasma ("PRP") products. The suit additionally named the U.S. distributor of Estar's products (Eclipse Aesthetics LLC) and one of Eclipse's customers (Healeon Medical Inc.). Although Plaintiff alleges both direct infringement and indirect infringement claims in its Complaint, none of these defendants could possibly be liable for direct infringement because they do not practice the methods claimed in the patent in suit. Counsel for Plaintiff has acknowledged as much in conferences with this Court where arguments were presented in connection with the venue motion that customers are material witnesses because they are the only direct infringers.

Plaintiff has proceeded in the present case without a defendant that is directly infringing and is pursuing theories of contributory infringement and active inducement of infringement. Plaintiff has not sought to amend its pleadings to include a direct infringer, but has now filed a separate lawsuit claiming patent infringement against three customers of Eclipse. The direct infringement claim is based on representative claim 20 of the patent at issue that requires the addition of a cell extract and the admixing of the cell extract with a platelet concentrate. As far as Eclipse is aware,

these two steps are not performed by any of Eclipse's customers. The three customers who have been sued by Plaintiff have also given declarations that confirm they are only using the Eclipse PRP product to prepare PRP and are not providing cell extracts or admixing cell extracts to the PRP prior to applying the PRP to the patient. Thus, it is apparent that the infringement suit against the customers of Eclipse was filed only for the purposes of buttressing Plaintiff's argument against the venue motion, harassing Eclipse's customers, and serving as a shield against false statements made by Plaintiff's sales representatives in their attempts to avert sales of the Eclipse PRP products from both existing and prospective customers.

Eclipse's customers are medical professionals (physicians) who utilize the Eclipse PRP product in connection with a medical procedure performed on a patient's body. Physicians and related entities are immune from claims of direct infringement and induced infringement claims arising out of medical procedures under 35 U.S.C. 287(c). Moreover, because none of the three physicians in the customer lawsuit have performed the admixing step required by claim 20, there is no plausible claim of direct or indirect infringement. Therefore, the claims of patent infringement against Eclipse's customers were brought in bad faith, and the Court should not allow this sham litigation against Eclipse's customers to proceed.

For these reasons, Defendant requests a preliminary injunction enjoining the continuance of the customer suit; preventing the filing of additional lawsuits against other customers of Eclipse or Healeon; preventing Plaintiff from making additional claims or representations, either oral or written, outside of this lawsuit that any of the PRP products manufactured by Estar infringe any claim of the patent in suit. Additionally, subject to its request for a preliminary injunction as to the claims against customers, Defendants Eclipse and Healeon are requesting a severance and stay of the claims against them pending the outcome of the claims against the manufacturer Estar.

II. Factual Background

A. Litigation Background of the Parties.

The present case is only the latest in a string of litigation between Eclipse and RegenLab. There have been several litigation battles between these two parties on multiple fronts and levels. First, an action was filed by Eclipse Aesthetics, LLC, ("Eclipse") in Texas state court asserting tortious interference with current and prospective business relationships, and business disparagement. (Dkt. 49, App. 005-007.) The Texas action was filed in response to a disparaging email sent out by RegenLab USA on April 25, 2014. (Dkt. 49, App. 004-005, 010-012.) That email purported to "compare" RegenLab's PRP kit to Eclipse's PRP kit, and went further to claim that Eclipse's PRP kit would cause fever and inflammations by bacteria, similar statements were also made by RegenLab in a letter to the FDA. (Dkt. No. 49, App. 021, 058-067.)

On November 19, 2015, Eclipse, had to file an action for violation of the Lanham Act in response to RegenLab USA's use of the Eclipse mark "Eclipse PRP" in a RegenLab Google Adword campaign. (Dkt. No. 49, App. 071-078.) RegenLab USA removed the state court action to federal court on May 27, 2016 and these two matters were then consolidated on September 12, 2016. (Dkt. No. 49, App. 088-097.) RegenLab USA and other defendants subsequently filed a set of counterclaims against Eclipse as well as a third party complaint against third party defendants Dr. Sanjay and Amy Batra. (Dkt. No. 49, App. 098-112.)

Now, Eclipse is having to endure another litigation offensive relating to its Eclipse PRP product. (Dkt. No. 1.) There has never, in the past or the present, been infringement of the '957 patent by Eclipse. Going even further, RegenLab USA recently filed baseless lawsuits against

Eclipse customers as well without investigating the alleged infringement by these customers. (Dkt. No. 1, Case No. 1:17-CV-03845.)

B. The Background of Platelet Rich Plasma ("PRP").

The development of PRP technology began several decades ago as doctors learned the advantages of centrifuging plasma into separated components. In 1998, Dr. Robert Marx published his paper entitled "Platelet-rich plasma Growth factor enhancement for bone grafts" in Oral and Maxillofacial Surgery, and for many, this is the start of modern PRP development. *See* Robert E. Marx et al., *Platelet-rich plasma Growth factor enhancement for bone grafts*, 85 ORAL AND MAXILLOFACIAL SURGERY 6, 638-46 (1998).

Although used experimentally for many purposes, PRP now is primarily used for three purposes: enhanced wound healing, pain management, and aesthetics. As demonstrated in *Marx*, a surgeon can utilize PRP to increase the platelet growth factors and in combination with bone graft materials can speed recovery time for orthopedic surgeries. *Id.* *Marx* describes utilizing the PRP in a surgical environment, where blood is drawn through central venous catheter, centrifuged at 5600 RPM, the PRP and Platelet Poor Plasma ("PPP") are then separated, and the remaining mixture is centrifuged again at 2400 RPM. There are also tabletop centrifuges that allow the process and procedure to be performed in a doctor's office as well. *See* HarvestTech, *Global Products :: Wound Healing*, Harvest, (March 14, 2006, Internet Archive), https://web-beta.archive.org/web/20060314171412/http://www.harvesttech.com/IntlHemo.htm.

Today, these in-office systems are utilized by dermatologists to create PRP for use in hair growth and cosmetic treatments. These treatments are typically completed using an unaltered form of raw concentrated PRP. For hair growth treatments, for example, the PRP is prepared and then injected directly into the scalp to increase the natural growth factors around hair follicles

and increase the chance of natural growth. In cosmetic procedures, the PRP is prepared and then spread or injected just below the skin surface. A micro needling procedure can also be utilized to reduce the appearance of wrinkles and skin wear naturally by causing an increase in the production of natural collagen.

III. ARGUMENTS

A. Suits Against Medical Service Providers Should Be Enjoined

Plaintiff has filed a new lawsuit against customers of Eclipse in an attempt to garner venue over Eclipse. *See RegenLab USA LLC v. Raj Kanodia, M.D. et al.*, No. 1:17-CV-03845-ALC (hereinafter, the "Customer Suit"). The suit was filed the same day as the Supreme Court's decision in *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, No. 16-341, 2017 WL 2216934 (May 22, 2017 (Slip copy). Defendants assert that this lawsuit was filed solely for the purposes of gaining a venue leverage over defendants, and providing the ability for Plaintiff to use the lawsuit as a scare tactic with Eclipse's customers.

An injunction preventing the filing of a lawsuit against customers is proper in the case of bad faith allegations of patent infringement. *See Katz v. Lear Siegler, Inc.*, 909 F.2d 1459 (Fed. Cir. July 25, 1990); *ProBatter Sports, LLC v. Joyner Techs.*, Inc., 463 F. Supp. 2d 949 (N.D. Iowa Nov. 3, 2006). There are also cases that have enjoined communications to customers, including threats of litigation. *See Johnson Elec. North America, Inc. v. Mabuchi Motor America Corp.*, 1986 U.S. Dist. LEXIS 25967, 1986 WL 5385 (S.D.N.Y. May 2, 1986); *Etna Products Co. v. Finney*, 1993 U.S. Dist. LEXIS 2242, 1993 WL 60708 (S.D.N.Y. Feb. 26, 1993); *Lucasey Mfg. Corp. v. Anchor Pad Int'l, Inc.*, 698 F. Supp. 190 (N.D. Cal. Apr. 26, 1988).

In *ProBatter*, the district court noted that the accused infringer brought allegations of bad faith against the patentee because they were trying to: "(1) intimidate Joyner's customers, (2) increase Joyner's litigation costs and (3) unnecessarily burden Joyner 'with multiple indemnification obligations for pointless, redundant litigations.'" *ProBatter*, 463 F. Supp. 2d at 953 (internal citation omitted). In the same way, RegenLab is attempting to intimidate Eclipse's customers, increase its litigation costs, and unnecessarily burden Eclipse with redundant litigation costs if customers request and Eclipse agrees to indemnification of those customers. In finding an injunction proper, the court in *ProBatter* noted that the same patent was at issue, and similar facts were alleged in the later filed customer suits. *ProBatter*, 463 F. Supp. 2d at 955-957. Likewise, the facts and claims alleged in the Customer Suit here are duplicative of the instant suit.

The Federal Circuit has upheld injunctive relief against a patentee where a manufacturer of the product at issue was already in litigation with the patentee. *Id*. In *Katz*, the Federal Circuit pointed out that at the very basic roots of the proceeding the manufacturer is the real party in interest, not the customer, and that either for good business or by contract, a manufacturer will often need to protect its customers from lawsuits. *Katz*, 909 F.2d at 1464. The Supreme Court has also recognized that subsequent suits against customers can be enjoined pending the outcome of the manufacturer suit. *See Kerotest Mfg. Co. v. C-O-Two Fire Equipment Co.*, 342 U.S. 180 (Jan. 2, 1952). In *Katz*, the court held that the customer suit could be enjoined even without a showing of bad faith, and based on judicial economy and the advancement of the case as a whole by letting the claims against the manufacturer be resolved first. *Katz*, 909 F.2d at 1464.

Plaintiff has proceeded much like the patentee in *ProBatter*, in that they have proceeded against not only Eclipse but also customers of Eclipse. *See ProBatter*, 463 F. Supp. 2d at 951-953. Because many of the same facts, and the same controversy is involved in the customer lawsuit it should be enjoined like the customer suits in *ProBatter*. Thus, Plaintiff should be enjoined from continuing further litigation in the pending Customer Suit, and enjoined from pursuing additional litigation against other customers of Eclipse because of judicial economy.

i. Injunctive Relief is Proper in Order to Stop Needless Litigation Against Customers.

Courts in the Second Circuit as well as other courts from around the country have held that indirect infringement claims, and direct infringement claims filed against customers can be enjoined. *See Bechik Prods. v. Flexible Prods.*, 225 F.2d 603 (2d Cir. 1955); *Johnson*, 1986 U.S. Dist. LEXIS 25967, at *3-7; *Ideal Toy Corp. v. Kenner Prods. Div. Of Gen. Mills Fun Group*, 1977 U.S. Dist. LEXIS 13291 (S.D.N.Y. 1977). Moreover, there have also been cases where courts have restricted the language of letters sent to accused customer infringers of a manufacturer pending the outcome of a manufacturer suit. *See Etna*, 1993 U.S. Dist. LEXIS 2242, at *4-8; *T. J. Roaco*, 1985 U.S. Dist. LEXIS 24259, at *2-13. Thus, it is under these cases, principles and policies that Defendants are requesting the enjoining of further proceedings involving customers of Eclipse, and the enjoining of further letters threatening customers of Eclipse with baseless litigation.

Defendants will acknowledge that a patent owners ordinarily has the right to make others aware of their patent rights, but that right only extends to good faith claims of infringement. Defendants should not be permitted to assert any rights against physicians who are immune from suit under Section 287(c) or for whom Plaintiff has no evidence are practicing all the steps of the

asserted method claim. Any communication allowed to Plaintiff should make clear that the Estar products at issue in this lawsuit are not infringing products, that there are in fact no product claims in the patent, and should outline the steps that must be taken to infringe the asserted method claim. *See Etna*, 1993 U.S. Dist. LEXIS 2242, at *4-8; *T. J. Roaco*, 1985 U.S. Dist. LEXIS 24259, at *2-13.

In *Etna*, the district court found that because the patentee did not produce its product with the same structural limitations as found in its patent, and the accused product was also lacking the same structural feature, an injunction was proper to prevent irreparable harm due to a loss of good will and reputation. *Etna*, 1993 U.S. Dist. LEXIS 2242, at *4-8. The patentee proceeded to send letters to customers of the accused manufacturer letting them know the patentee would be seeking court ordered injunctions and treble damages against the manufacturer as well as taking action against the customers. *Id*. Etna (the accused manufacturer) lost sales to the patentee and was forced to make indemnification agreements or provide indemnification to some customers to ensure their business. *Id*. at *4. The court found that while communications and notices of a patent and a patentee's rights, along with the litigation can be pursued in good faith, when there is bad faith in the assertion for the purpose of disrupting a competitor's business, these same actions can be enjoined. *Id*. at *6-7.

Another Second Circuit case, *Johnson Electric*, provides a discussion and illustration of an injunction based upon multiple customer lawsuits. *Johnson*, 1986 U.S. Dist. LEXIS 25967, at *6-7. The court in *Johnson* pointed out that a patentee's rights would not be substantially impaired against an infringer or contributory infringer where the litigation resulted from suing a customer, and there is ongoing litigation between the patentee and accused manufacturer that

could satisfy the damages of the customer as well. *Id*. at *4-6. Based on this premise, the court enjoined an independent action against customers of the manufacturer.

ii. Likelihood of Success on the Merits

As noted by the court in *Etna*, along with irreparable harm there must also be a likelihood of success on the merits or a sufficiently serious question going to the merits and a balance of hardships that tips in favor of the moving party. *Etna*, 1993 U.S. Dist. LEXIS 2242, at *6-7. In the present case, as discussed above, Defendants will likely succeed on the merits or have shown a serious question going to the merits because 1) there is no infringement; and 2) any direct infringement by Defendants' customers is immune from suit under 35 U.S.C. § 287(c). Plaintiff does not have a plausible argument to the contrary.

There is also a serious question of the validity of the patent-in-suit. The applicant for the patent in suit published a presentation during the 2004-2005 timeframe that indicates public use and sales prior to the priority date of the invention. Based on the fact that this material, along with a sales brochure and instructions were published on Regenlab's website, there are public uses that were documented and published in public form prior to the priority date and/or the critical date of the patent at issue. (Exhibit 1 & 2, App. 1-75.) Thus, the methods claimed in the patent in suit were within the public domain or knowledge prior to the priority date and/or critical date of the patent rendering the patent invalid and unenforceable.

iii. Irreparable Harm

A party seeking an injunction must show irreparable harm if an injunction is not issued. *Etna*, 1993 U.S. Dist. LEXIS 2242, at *6 (internal citations omitted). This irreparable harm can come from a number of sources, namely lost sales and good will. Id. at *6-7. Lost reputation

and/or good will is evidence of irreparable harm and can be illustrated through communications from customers concerned with the ongoing litigation matter. *Lucasey*, 698 F. Supp. at 192. Courts have noted that this lost reputation or good will can continue if communications from a patentee continue and thus would create irreparable harm. *Etna*, 1993 U.S. Dist. LEXIS 2242, at *6-7; *Lucasey*, 698 F. Supp. at 192.

In the present case, RegenLab has already proceeded with direct attacks on customers of Eclipse while also having previously sued Eclipse. Thomas O'Brien has stated in his declaration in support of this motion that there is a strong likelihood of injury to Defendant Eclipse if the attacks from Plaintiff are not stopped. (Decl. of Thomas O'Brien, App. 79, ¶¶ 13-15.) Moreover, the continued press releases and attacks by the Plaintiff have created serious concerns and worries for customers of Eclipse that have resulted in some customers discontinuing ongoing relations with Eclipse. (Decl. of Thomas O'Brien, App. 79, ¶¶ 14-15.) Furthermore, some customers have stated they want to avoid a lawsuit and reduce any risk that they will have if RegenLab continues its ruthless attack on Eclipse and its customers. (Decl. of Thomas O'Brien, App. 79, ¶¶ 14-15.) Along with this loss of reputation and good will, Eclipse has already seen customers leave Eclipse for other PRP vendors because of the threat or perceived threat of potential litigation. (Decl. of Thomas O'Brien, App. 79-80, ¶¶ 14-19.)

Eclipse receives a majority of its revenues from the sales of its Eclipse PRP product, and if that product is continually disparaged and attacked, sales could be severely curtailed to the point that Eclipse is unable to recover. (Decl. of Thomas O'Brien, App. 79-80, ¶¶ 13, 17.) Thus, there will be irreparable harm or at the very least a strong likelihood of irreparable harm if the ongoing attacks against Eclipse and its customers are not tempered. These harms cannot and will not be satisfied by any judgment of a court of law, due to there being no ability to quantify the

amount of the damages. *Etna*, 1993 U.S. Dist. LEXIS 2242, at *6-7; *Lucasey*, 698 F. Supp. at 192.

Eclipse is asking this Court to prevent the harassment of its customers with threats and actual lawsuits, when there is already litigation ongoing between Eclipse and RegenLab, as well as the manufacturer Estar. There is past, present, and potential future irreparable harm from Plaintiff's continued false allegations of infringement and threats of suit against the customers of Eclipse.

iv. Plaintiff's Suit against the Three Doctors is Baseless.

The Customer Suit that Plaintiff has filed is against doctors, medical professionals and related entities who are providing medical services and procedures for their patients. (Decl. of Drs. Kanodia, Daly, and Fruitman, App. 94-108.) These medical providers are protected from method patent infringement suits under the patent laws. *See* 35 U.S.C. § 287(c). Additionally, there is no infringement of the asserted '957 patent by the doctors that have been sued, and the evidence will show that the '957 patent is invalid based on both the actions of the applicant of the patent in suit as well as the well-established prior art at the time of the filing of the application for patent.

The complaint of the Customer Suit mirrors the factual allegations of the complaint in the present case, with some additions with respect to alleged conduct by the physicians. For example, Plaintiff alleges that the video demonstration of PRP by Defendant Kanodia illustrates a direct infringement of the representative claim 20 even though the admixing step of claim 20 is not shown. (Customer Suit Complaint, Dkt. No. 1, ¶ 45.) The video does not provide any illustration, instruction, or use showing the providing of a cell extract nor does it illustrate the admixing of a cell extract with the platelet concentrate. *PRP Video*, Dr. Raj Kanodia Plastic

Surgery (Oct. 24, 2016), http://www.drkanodia.com/plastic-surgeon-beverly-hills/interview-videos/.[1]

v. 35 U.S.C. § 287(c) Immunity Applies.

The customers of Eclipse that Plaintiff sued are medical professionals who are immune from a claim of patent infringement related to the use of the Eclipse PRP product to perform a medical procedure on a patient. *See* 35 U.S.C. § 287(c); (Decl. of Thomas O'Brien, App. 76-93, and Drs. Kanodia, Daly and Fruitman, App. 94-108.) Therefore, Plaintiff has brought the customer suit against medical professionals that Plaintiff knows are protected by statutory immunity. (Decl. of Thomas O'Brien, App. 76-93, and Drs. Kanodia, Daly and Fruitman, App. 94-108.)

The relevant portion of the immunity statue states that in connection with "a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity." 35 U.S.C. § 287(c). The term "medical activity" is defined as "the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent." 35 U.S.C. § 287(c)(2)(A). The statute further excludes from the immunity provision the activities of a person that is directly related to the commercial

[1] Can also be found at https://youtu.be/VtJl_e-t8FU.

development, sale, manufacture, importation or distribution of a machine, manufacture, or composition of matter that is regulated by the FDA. 35 U.S.C. § 287(c)(3).

In the case of the doctors sued by RegenLab, the doctors are not involved in the commercial development, sale, manufacture, importation or distribution of Eclipse PRP products. (Decl. of Drs. Kanodia, Daly and Fruitman, App. 94-108.) These doctors only use the Eclipse PRP product in connection with performing procedures on their patients. (Decl. of Drs. Kanodia, Daly and Fruitman, App. 94-108.) Thus, these doctors are immune from suit under section 287(c), and there are no exceptions that are applicable to them.

vi. The physicians do not infringe the asserted claim.

Plaintiff asserts and alleges in the Customer Suit that claim 20 is infringed. Claim 20 reads as follows:

> 20. A process for the preparation of a cell composition, comprising the steps of:
>
> a) centrifuging whole blood in a separator tube selected from:
>
> a glass separator tube containing a polyester-based thixotropic gel and a buffered sodium citrate solution at 0.10 M; or
>
> a polyethylene terephthalate separator tube containing a thixotropic gel formed by a polymer mixture and an anhydrous sodium citrate at 3.5 mg/mL; wherein the centrifugation step is performed at a force of about 1500 g up to about 2000 g for a sufficient length of time to form a barrier between full plasma containing platelets, lymphocytes and monocytes and a pellet containing the erythrocytes;
>
> b) optionally separating enriched platelet rich plasma from full plasma by removing about half of the supernatant formed during the centrifuging step, said removed supernatant containing platelet poor plasma, wherein the separation is made by collecting the supernatant from atop of said barrier; and wherein the enriched plasma is enriched in leucocytes, thrombocytes and adhesion proteins as compared to native whole blood;
>
> c) re-suspending the enriched platelet rich plasma or the full plasma to form a platelet concentrate;
>
> d) providing a cell extract comprising cells selected from the group consisting of adipocytes; adipose stem cells; fat cells; corneal cells; corneal limbal stem cells; cornea keratinocytes; dermal cells; fibroblasts; melanocytes; Langerhan's cells; bone marrow cells; muscle cells; satellite stem cells; myoblast

> progenitor stem cells; osteoblasts; chondrocytes; periosteal membrane cells; umbilical cord stem cells; stem cells; Schwann cells; cartilage cells; ligament cells; tendon cells; connective tissue cells, gingival cells and pancreas islet cells; and
>
> e) admixing the platelet concentrate obtained under step c) with the cell extract of step d).

Plaintiff further alleges that a video from Dr. Kanodia's website is evidence of infringement of the '957 patent. *See* (Doctor Lawsuit Complaint, Dkt. No. 1, ¶ 45.) However, a review of this video will show that there is no cell extract provided from a biopsy, harvest, culturing, or otherwise, nor is there any admixing of the platelet concentrate with a cell extract as required by steps d) and e) of claim 20.[2] *PRP Video*, Dr. Raj Kanodia Plastic Surgery (Oct. 24, 2016), http://www.drkanodia.com/plastic-surgeon-beverly-hills/interview-videos/. Finally, the video shows only a use of the PRP in its raw and natural concentrate form. All of the doctors in the customer suit further affirm in their declarations that they are not mixing anything with the prepared PRP before applying it to their patients. (Decl. of Drs. Kanodia, Daly, and Fruitman, App. 94-108.) Thus, there can be no possible infringement of the representative claim 20 by the customers.

Courts in this district have found that when there appears to be no infringement based on the initial review of the products, an injunction can be granted. *See Etna*, 1993 U.S. Dist. LEXIS 2242, (S.D.N.Y. Feb. 26, 1993). Here the patent in suit claims methods and Plaintiff asserts there are no substantial non-infringing uses for PRP. Yet, there are several illustrations of

[2] Examples of providing a cell extract from the patent in suit include: skin biopsy samples removed from patients (column 26, lines 61-67; column 30, lines 53-54), skeletal muscle biopsy from the Vastus lateralis muscle group, primed a day (column 29, lines 20-22); standard culture methods (column 31, lines 40-43; column 32, lines 39-40; column 32, lines 53-53.); cartilage biopsy (column 31, lines 60-61; column 32, lines 8-11); harvesting from the buccal side of the mandibular body of a dog (column 33, lines 18-21); corneal biopsy (column 34, lines 9-15); harvesting of hip bone marrow (column 34, lines 57-60); nerve biopsy of either the "N. Saphenous of [sic] N. Suralis in the lower extremity" (column 35, lines 9-14); open biopsy of pancreas islet cells (column 35, lines 32-37); bone biopsy (column 35, lines 53-57).

substantial non-infringing uses described in the patent-in-suit, which allows for the use of not only Defendants' products but also third party products as well. *See* U.S. Patent No. 8,529,957, Col. 24, Line 54 – Col. 26, Line 26, Examples 2 and 3. Like the non-infringing examples provided in the patent in suit, the Kanodia video also does not show the provision of a cell extract as required in claim 20 of the patent, nor is there any admixing of a cell extract with the prepared platelet concentrate. (Decl. of Thomas O'Brien, App. 76-93, and Decl. of Drs. Kanodia, Daly and Fruitman, App. 94-108.)

B. Improper Communications Regarding Patent Infringement Must Be Enjoined

There have been several cases in this and other districts throughout the country where injunctive relief has been granted because of harm that would come to the upstream business due to threats and communications made to downstream customers and end-users. *See Johnson Elec. North America, Inc. v. Mabuchi Motor America Corp.*, 1986 U.S. Dist. LEXIS 25967, 1986 WL 5385 (S.D.N.Y. May 2, 1986); *Etna*, 1993 U.S. Dist. LEXIS 2242; *Lucasey Mfg. Corp. v. Anchor Pad Int'l, Inc.*, 698 F. Supp. 190 (N.D. Cal. Apr. 26, 1988). Injunctive relief is likewise proper in this case.

i. Plaintiff's Communications to the Doctors and Eclipse's Customers Are Made in Bad Faith.

Courts such as those in *Etna* and *T.J. Roaco* have enjoined a patentee from sending threatening letters to the customers of a manufacturer that is already in litigation regarding the same patent. *See Etna*, 1993 U.S. Dist. LEXIS 2242, at *4-8; *T. J. Roaco, Ltd. v. Syntex Pharms. Int'l, Ltd.*, 1985 U.S. Dist. LEXIS 24259, *2-13 (D.N.J. Aug. 15, 1985). Specifically, in *T.J. Roaco* the court found that the accused manufacturer would be seriously damaged if the

patentee were allowed to continue threatening suits that included awards of treble damages and other punitive damages or the like. *T. J. Roaco*, 1985 U.S. Dist. LEXIS 24259, at *10-12. Furthermore, damage to reputation and good will can serve as the irreparable harm and bad faith can be shown where the products do not conform to the claims of the patent at issue (i.e., there is no infringement). *Etna*, 1993 U.S. Dist. LEXIS 2242, at *4-8. Bad faith allegations can include making misstatements, or making statements that are unsupported by the allegations of the complaint; there must also be clear descriptions of the alleged infringement that can allow the accused infringer to determine if there has been any potential infringement. *Lucasey*, 698 F. Supp. at 193. Likewise, in the present case, RegenLab cannot possibly prevail on its claims that the Eclipse PRP product is infringing.

An injunction for the prevention of communications with potential infringers that are customers of the manufacturer or other defendant is proper if bad faith is properly alleged. In the present case, RegenLab has continually accused the Eclipse PRP product of infringement and made statements that the product infringes to Eclipse's customers while also arguing that it is a method that can only be infringed by someone performing all the steps. *See* (Hearing Transcript, Dkt. No. 67, Page 8, Lines 17-22.) Thus, RegenLab has continually sent and published statements in an effort to bully, harass, and intimidate Eclipse's customers and should be enjoined in order to stop the bullying and harassment of Eclipse's customers.

Furthermore, there is no infringement. Physicians in the aesthetics industry to which Defendants sell their products do not provide or admix any cell extracts with the PRP products. (Decl. of Thomas O'Brien, App. 76-93.) Additionally, there is clearly no infringement by the doctors sued by RegenLab. (Decl. of Drs. Kanodia, Daly and Fruitman, App. 94-108.) Furthermore, the customers that Plaintiff have sued in the Customer Suit are medical

professionals that are protected under section 287(c) from these types of law suits when there is a medical procedure involved. *See* 35 U.S.C. § 287(c). Because these medical professionals have statutory immunity, an action against them is brought in bad faith.

This non-infringement is best shown by the very video that Plaintiff points to in the Customer Suit. The video illustrates and informs a patient of what to expect in a PRP procedure. Blood is drawn from the patient into a vial, which is then placed in a centrifuge for platelet separation; upon separation the platelet rich plasma (enriched plasma) is removed and then directly applied to the scalp of the patient in a hair loss prevention procedure. There is clearly no cell extract provided, and if there is no cell extract, provided there can be no admixing of a cell extract either.

Moreover, the examples in the patent at issue starting in Col. 21 illustrate that cells are harvested, gathered, cultured, or otherwise utilized from a biopsy or other procedure and then purposefully mixed with the platelet concentrate. *See* '957 patent Col. 21-Col. 36. These examples illustrate that the procedure provided for in the Kanodia video does not perform the required step of providing a cell extract. Rather, the physician simple creates PRP and injects it into the patient's scalp.

Upon information and belief, RegenLab withheld material information from the USPTO and/or materially did not provide a clear understanding of the relevant technology in the field at the time of the invention. Furthermore, RegenLab may have publicly used and/or sold their products utilizing the same method as the representative claim 20 prior to the priority date and/or the critical date of the patent at issue. Both of these are illustrated in Exhibits 1 and 2 attached herein, where Exhibit 1 is the presentation that is missing several slides that Defendants believed have relevant information on them. (Exhibit 1, App. 1-56.) Additionally, Exhibit 2 is the sales

brochure and instructions for the RegenLab PRP product on sale in at least May 2005. (Exhibit 2, App. 57-75.) It is upon information and belief that the RegenLab PRP product practicing the method of representative claim 20 was available prior to that date and the priority date and/or critical date of the patent at issue.

ii. Neither Fair Reporting Nor Litigation Privilege Apply to Bad Faith Communications

A party is not permitted to make false allegations in a complaint and then use the litigation privilege to avoid a claim of disparagement. *Bilinski v. Keith Haring Found., Inc.*, 96 F. Supp. 3d 35, 48-49, n.13 (S.D.N.Y. Mar. 6, 2015). In the instant case and in the Customer Suit, Plaintiff repeatedly makes claims that the PRP products manufactured by Estar is infringing when there is no dispute that the product itself does not infringe any claim of the patent. Plaintiff has threatened other customers by pointing to the Customer Suit when attempting to divert sales from Eclipse. Plaintiff has never explained in the lawsuit, in its letters to customers, or in any communications that the patent in suit covers a method, not a product. They would rather customers continue to believe that the product itself is what is allegedly infringing. Because Plaintiff has made these allegations in bad faith, the Customer Suit is a sham litigation to which the litigation privilege does not apply.

Moreover, the communications made by Plaintiff to doctors through cease and desist letters and the press release issued by the Plaintiff fail to properly and accurately report the allegations in the complaint. (Decl. of Thomas O'Brien, Ex. 1, App. 83-86.) When statements in communications go further than that in the complaint, or are made with reckless disregard for the facts resulting in a statement that is not substantially accurate, the privileges cannot apply. *Bilinski*, 96 F. Supp. 3d at 48-49, n.13. In *Bilinski*, statements were made in a press release that

went further than those from a previous agreement, and thus, were not substantially accurate. *Bilinski*, 96 F. Supp. 3d at 48-49. In the present case, the statements in the press release repeatedly states that the customers directly infringe by using and/or selling the Eclipse PRP product. (Decl. of Thomas O'Brien, Ex. 2, App. 87-90.) As admitted by Plaintiff, this is a method patent and therefore cannot be directly infringed by any product only through the performance of steps by an end user. (Hearing Transcript, Dkt. No. 67, Page 8, lines 17-22.) Furthermore, the communications sent to the doctors was purposefully sent after the commencement of litigation in order to gain an absolute privilege rather than a qualified one. *Front, Inc. v Khalil*, 24 N.Y.3d 713, 718-720 (N.Y. Feb. 24, 2015). As the court in *Front* found, there is a qualified privilege that can be lost prior to the commencement of litigation due to reckless and malicious actions taken by attorneys on behalf of their clients, and in particular, if those actions were taken in bad faith. *Front,* , 24 N.Y.3d at 718-20. In the present case, counsel waited to inform the doctors until after the commencement of litigation to gain this absolute privilege even though their actions and communications were reckless and malicious, bullying tactics raised in bad faith to cause serious harm and disruption to Eclipse's business. (Decl. of Thomas O'Brien, App. 76-93.) These statements should fall under the qualified privilege, not the absolute privilege because of their reckless, malicious, and bullying tactics were raised in bad faith as there is no infringement and the patent is invalid. Thus, these improper communications and suits should be enjoined.

C. Claims Against Resellers Should be Stayed After Entry of Injunction

In addition to a desire to stop the Customer Suit from moving forward to protect its customers, Defendants Eclipse and Healeon also request the Court to sever and stay the proceeding against them until the suit against manufacturer Estar is completed. *See In re*

Nintendo of Am., Inc., 756 F.3d 1363 (Fed. Cir. June 25, 2014). This method of judicial economy and management has been approved and utilized by the Federal Circuit, as well as district courts. *See Nintendo*, 756 F.3d at 1365-1366; *In re Toyota Motor Corp.*, 747 F.3d 1338 (Fed. Cir. Apr. 3, 2014). While the direct application of the customer suit exception cannot be utilized, the rationales and policies behind it can be, much in the same way the Federal Circuit applied them in *Nintendo*. *Nintendo*, 756 F.3d at 1365-1366. The manufacturer case would resolve many of the issues that would be handled in the customer suit as well. *Id.* The patentee is only able to recover once for the same product, or in other words, if Plaintiff recovered against the manufacturer and that recovery included the sales to the customers (resellers) they could not then seek to recover against the customers as well. *Id.* at 1366.

The court in *In re Toyota* reviewed the record and came to a similar conclusion as the court in *Nintendo*. *Toyota*, 747 F.3d at 1340-41. In *Toyota*, the patentee had filed suit against a customer and the manufacturer in a district close to the customer. *Id.* at 1339-40. The district court analyzed the transfer motion and factors without considering what would happen to the case if the customer was severed and stayed. *Id.* at 1340-41. The Federal Circuit upon review determined that the transfer factors heavily favored transfer but for the customer, and then ordered the denial of stay, sever and transfer vacated and remanded the case for review. *Id.* (The district court then followed the opinion of the Federal Circuit, severing and staying the claims against the customer pending the outcome of the transferred manufacturer claims).

As noted in the *Katz* case, the ultimate goal of the customer suit exception is judicial economy and the prevention of duplicative actions. An injunction preventing the continuance of the Customer Suit will clearly be more economical for the Court and prevent an almost duplicate action to the present one from moving forward. Moreover, a stay of Eclipse and Healeon will

provide for the manufacturer and Plaintiff to proceed with their presumed invalidity and non-infringement claims and would ultimately simplify any potential proceedings between Plaintiff and Defendants.

Finally, the complaint in both the present case and the Customer Suit alleges that there is direct and indirect infringement of the patent at issue. Thus, it is clear that if one case moves forward it will simplify the issues in any of the related proceedings. Eclipse and/or Healeon are merely resellers of the Estar product, and no changes are made to the product after it has left Estar. The customers of Eclipse are medical professional who utilize the product during medical procedures and purchase it from the resellers Eclipse and/or Healeon. Therefore, Eclipse and Healeon as mere resellers of the product should be severed and stayed from the present proceedings, subject to their motion to dismiss or in the alternative transfer.

IV. Conclusion

Because of the case law and facts cited above, this Court should grant Defendants motion for an injunction against Plaintiff enjoining them from continuing the suit against the customers of Eclipse, and should also enjoin Plaintiff from further threatening customers of Defendants during the pendency of the present case. Defendants' motion for a stay of this present case against them should also be granted as they are merely resellers of the products and not the manufacturer. Thus, Defendants respectfully requests this Court to grant the requested injunctions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that counsel for Plaintiff Regenlab USA LLC were served with a copy of this document via the Court's CM/ECF system on July 6, 2017.

s/Vincent J. Allen
Vincent J. Allen